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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,050	01/15/2002	Charles M. Cohen	CIBT-P05-518	3705
28120	7590	09/20/2004	EXAMINER	
ROPE & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624				ROMEON, DAVID S
ART UNIT		PAPER NUMBER		
1647				

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/050,050	COHEN ET AL.
	Examiner	Art Unit
	David S Romeo	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 August 2002.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 66-68 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 66-68 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>04/29/2002</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

The preliminary amendments filed 08/13/2002 and 01/15/2002 have been entered.

Claims 66-68 are pending and being examined.

5

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 10 Claims 66-68 are rejected under 35 U.S.C. 112, second paragraph, as being
indefinite for failing to particularly point out and distinctly claim the subject matter
which applicant regards as the invention.

Claim 66 recites the limitation "said composition" in line 8. There is insufficient
antecedent basis for this limitation in the claim. The metes and bounds are not clearly set
forth. Claims 67, 68 depend from claim 66 and also share this deficiency. It is suggested
15 that the claim 66 recite "a composition comprising an isolated morphogen ..." in line 2.

Double Patenting

- 20 The nonstatutory double patenting rejection is based on a judicially created
doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the
unjustified or improper timewise extension of the "right to exclude" granted by a patent
and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d
1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed.
Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*,
25 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163
USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be
used to overcome an actual or provisional rejection based on a nonstatutory double
patenting ground provided the conflicting application or patent is shown to be commonly
30 owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5 Claims 66, 67 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,399,569. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

both sets of claims cover the administration of the same compound and/or
10 composition;

“protecting proliferating epithelial cells in a mammal from the cytotoxic effects of an agent that destroys epithelial cells” is a species of “limiting the proliferation of epithelial cells in a mammal;”

the patent’s claims 2-8 are species of the patent’s claim 1, and, therefore, are
15 species of the present application’s claims;

A later genus claim is not patentable over an earlier species claim.

Claim 68 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4 of U.S. Patent No. 6,077,823.

20 Although the conflicting claims are not identical, they are not patentably distinct from each other because:

both sets of claims cover the administration of the same compound and/or
composition;

a method for limiting the mitogenic activity of proliferating epithelial cells associated with psoriasis, as recited in claim 68, is viewed as a method treating psoriasis, as recited in the patent's claim 4;

5

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

10 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The present application is claiming priority under 35 U.S.C. 120 to earlier filed applications. Under 35 U.S.C. 120, the claims in a U.S. application are entitled to the 15 benefit of the filing date of an earlier filed U.S. application if the subject matter of the claim is disclosed in the manner provided by 35 U.S.C. 112, first paragraph in the earlier filed application.

The earliest filed application that discloses limiting the mitogenic of proliferation epithelial cells is 07/938,336, filed 08/28/1992. Accordingly, the effective filing date for 20 the presently claimed invention is 08/28/1992. Should Applicants disagree, it is incumbent upon applicants to provide the serial number and specific page number(s) of any parent application filed prior to 08/28/1992 which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to 25 08/28/1992.

The following rejection is based on an effective filing date of 08/28/1992 for the presently claimed invention.

Claims 66, 67 are rejected under 35 U.S.C. 102(b) as being anticipated by

u AR 9/14

KuberaSampath (U. S. Patent No. 4,968,590, cited by Applicants) in light of Rutherford

5 KuberaSampath discloses osteogenic devices comprising a matrix containing substantially pure mammalian osteogenic protein and methods of inducing endochondral bone growth in mammals (Abstract). The osteogenic protein is prepared from bovine bones (column 6, full paragraph 1).

Rutherford teaches that OP-1 and, to a lesser extent BMP-2 account for most of
10 the BMP activity extractable from bovine bone (page 223, column 1, full paragraph 2).

Accordingly, KuberaSampath discloses an isolated morphogen that meets the structural limitations of "(i)" and "(ii)". Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, the properties applicant discloses and/or claims, i.e., "(iii)," are
15 necessarily present in KuberaSampath's protein.

The recitation of "for limiting ... cells" is an intended use of the claimed method. The intended use does not result in a manipulative difference as compared to the prior art.

Conclusion

20 No claims are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571)272-0961.

25 IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEST FINAL (703) 872-9306
AFTER FINAL (703) 872-9307

Art Unit: 1647

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (571) 273-0890.

5 ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

10



DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

15

DSR
SEPTEMBER 9, 2004